REMARKS

Applicant respectfully requests favorable reconsideration in view of the following remarks. Applicant submitted a Response to Office Action on February 5, 2009. As set forth in the Notice of Non-Compliant Amendment, the claim status identifiers were asserted as not being proper. Although not set forth in the Notice, the Examiner explained that the claim status identifiers for claims 20 and 21 should have been listed as (Withdrawn) and not (Previously Presented). This Supplement Response lists the claim status identifiers as required by the Examiner and re-presents the previously made claim amendments and arguments.

No claims have been amended herein. Claim 7 was cancelled in a previous Response. Claims 8-13 and 17-19 have been withdrawn from consideration. Claims 1-6, 14-16, 20, and 21 are presented for the Examiner's review and consideration. Applicants believe the remarks herein serve to clarify the present invention and are independent of patentability.

In response to the Restriction Requirement, Applicants elect Group I (claims 1-6 and 14-16), with traverse. The Examiner interprets Group I as drawn to a method for rewarding disease management programme participants based on their participation in health-related programmes. Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter in this application.

Pursuant to 37 C.F.R. § 1.111 and §1.143, Applicants hereby traverse the requirement for restriction and request reconsideration thereof in view of the following remarks.

The Examiner asserts that Groups I and II are related as subcombinations disclosed as usable together in a single combination. The Examiner further asserts that each group has a separate utility; Group I as an incentive program and Group II as a method of treating tobacco addiction. Thus, the Examiner concludes that restriction is proper because the subcombinations are distinct from each other and separately usable.

Applicants respectfully disagree. Two or more claimed subcombinations are usually restrictable when the subcombinations do not overlap in scope and are not obvious variants. *See*

MPEP 806.05(d). In the instant case, both Groups are drawn to a method for incentivising members of a disease management programme to comply with the programme. The method includes, *inter alia*, three general steps; first defining parameters, referred to in the specification as "programme areas" or "measurables", by which to measure compliance with the disease management programme; next providing a system for awarding points to members according to compliance with the defined parameters; and allocating rewards to the members based on the amounts of acquired points. Both methods include these three general steps, however the method of Group I encompasses all programme areas, while the method of Group II encompasses selective programme areas, for example, an exercise program, a smoking program, and an education program. Thus, the claims of Groups I and II are both drawn to incentive programs which clearly overlap in scope, and therefore are not properly restrictable.

The courts have recognized that it is in the public interest to permit an applicant to claim several aspects of his/her invention together in one application, as the Applicants have done herein.

The CCPA has observed:

We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore describe in the manner required by 35 U.S.C. § 112, all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to another aspect of the invention. For example, in the instant case, Groups I (claims 1-6 and 14-16) and II (claims 20-21) encompass different aspects of the same method, wherein the method of Group II recites selective programme areas rather than all programme areas as in the method of Group I.

Furthermore, the Examiner classifies the invention of Group II in Class 514, subclass 813. The subject matter of Class 514, subclass 813 is defined by the USPTO as encompassing <u>compositions</u> for treating addiction to tobacco. *Emphasis added.* Neither Group includes claims

drawn to compositions for treating tobacco addiction or any other addiction. Group II encompasses a method which includes using test results as a measurable indicator of compliance with a program. Even if one were to assume incorrectly that some type of cotinine composition is claimed, the claims still could not be properly classified in Class 514, subclass 813, as cotinine is a metabolite of nicotine that evidences nicotine intake, and thus is used as a diagnostic and not as a composition for treatment.

Thus, in contrast to the Examiner's assertion, Group II (claims 20-21) can not be used as a method to treat tobacco addiction. As noted above, the claims do not recite any method for treatment of tobacco addiction or any other addiction. Nor do they recite any compositions for treatment of addiction. In these claims, a smoking programme is selected as one of the measurable parameters and whether a member is awarded points or not in this area is based upon results of a cotinine test. The instant invention is drawn to methods designed to encourage people to comply with a programme, measure their compliance, and reward them accordingly. No treatments or compositions are claimed.

Additionally, Applicants respectfully point out that claims 1-6 and 14-16 have already undergone several examinations on the merits. As established above, the methods of claims 1 and 20 overlap in scope. Thus, the Examiner should not be burdened by additional searching, as a search of the method should already have been conducted.

Applicants respectfully suggest that, in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. § 121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such

allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, *Studiengesellschaft Kohle GmbH v. Northern Petrochemical Co.*, 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In *Gerber Garment Technology Inc. v. Lectra Systems Inc.,* 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), the court held that § 121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the instant application, wherein a single inventive idea (method of incentivising compliance with a disease management programme) is claimed.

Based upon all of the above, Applicants respectfully request reconsideration and withdrawal of the restriction requirement.

In the event that the restriction requirement is made final, Applicants respectfully request that the withdrawn claims (claims 8-13 and 17-21) be rejoined and examined upon allowance of claims 1-6 and 14-16 in accordance with the procedure as set forth in MPEP 821.04.

Conclusion

In light of the foregoing remarks, the claims, as presented herein, are now in condition for an examination on the merits, and early action is respectfully requested. If any questions remain regarding this Response or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all

concerned. No fees are believed to be due at this time. However, please charge any fee required (or credit any overpayment) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 7802-A08-002).

Respectfully submitted,

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